

BROOKLYN OFFICE

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

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In re: ZYPREXA PRODUCTS LIABILITY  
LITIGATION  
-----x

CHARLENE FOLSE, et al.,

Plaintiffs,

-against-

ELI LILLY & COMPANY,

Defendant.  
-----x

**JACK B. WEINSTEIN, Senior United States District Judge:**

MEMORANDUM, ORDER  
& JUDGMENT

04-MD-1596 (JBW)

04-CV-1612 (JBW)

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## **I. Introduction**

Kevin Folse, a 35-year-old Louisiana man, died in his sleep in September 2002. Plaintiffs, Charlene Folse (Mr. Folse's widow) and Joshua James Folse (his son), attribute Mr. Folse's death to an allegedly lethal interaction between defendant Eli Lilly & Company's ("Lilly") antipsychotic medicine Zyprexa and the antidepressant medicine Celexa. They claim that Celexa prevented Mr. Folse's liver from clearing Zyprexa from the body, causing a toxic build-up of Zyprexa in Mr. Folse's blood, and ultimately his death. Plaintiffs contend that defendant is liable to them for failing to warn about the risks of a Zyprexa-Celexa combination. Another claim against Forest Laboratories, Inc. and Forest Pharmaceuticals, Inc., the manufacturers of Celexa, was dismissed by stipulation of the parties.

Lilly moves for summary judgment. Plaintiffs commenced this action in Louisiana state court in September 2003. It was removed to federal court and transferred to the Eastern District of New York pursuant to an order of the Judicial Panel on Multidistrict Litigation.

For the reasons indicated below, defendant's motion for summary judgment is granted.

## **II. History of Zyprexa Litigation**

This massive and highly complex multidistrict litigation has included claims brought by individual Zyprexa users, states, third-party payors, and other entities alleging physical or financial injury. Some 30,000 cases have been brought against Lilly by individual plaintiffs suffering from serious psychiatric problems who were treated with the Lilly antipsychotic drug Zyprexa. They principally allege that Zyprexa caused deleterious side effects of excessive weight gain, hyperglycemia, and diabetes; that Lilly misled them and their physicians about the

likelihood of these side effects; and that, had they or their attending physicians been aware of the risks, they would not have taken Zyprexa.

Litigation against Lilly for injuries allegedly caused by Zyprexa was initiated in this court in March 2004. *See Benjamin v. Eli Lilly & Co.*, No. 04-CV-893. Thousands of cases were then transferred here from federal district courts throughout the United States pursuant to an order of the Judicial Panel on Multidistrict Litigation. *See Letter from Multidistrict Litigation Panel to Clerk of the Eastern District of New York*, No. 04-MD-1596, Docket Entry No. 1, Apr. 14, 2004. Similar cases have been litigated in state courts. *See In re Zyprexa Prods. Liab. Litig.*, 239 F.R.D. 316 (E.D.N.Y. 2007) (“Memorandum on Cooperation Between Federal and State Judges”).

The individual Zyprexa user litigation has been administered as a quasi-class action. *See In re Zyprexa Prods. Liab. Litig.*, 467 F. Supp. 2d 256, 262 (E.D.N.Y. 2006) (“The court, magistrate judge and special masters will continue to administer this litigation as a quasi-class action.”); *In re Zyprexa Prods. Liab. Litig.*, 451 F. Supp. 2d 458, 477 (E.D.N.Y. 2006) (“Recognizing its obligation to exercise careful oversight of this national ‘quasi-class action,’ the court has already utilized its equitable power to limit attorneys’ fees and costs.”) (citation omitted); *In re Zyprexa Prods. Liab. Litig.*, 433 F. Supp. 2d 268, 271 (E.D.N.Y. 2006) (finding that individual Zyprexa user litigation “may be characterized properly as a quasi-class action subject to the general equitable power of the court”); *In re Zyprexa Prods. Liab. Litig.*, 424 F. Supp. 2d 488, 491 (E.D.N.Y. 2006) (same); *In re Zyprexa Prods. Liab. Litig.*, 233 F.R.D. 122, 122 (E.D.N.Y. 2006) (same).

Cooperation between federal and state courts has been encouraged at all stages of the *Zyprexa* litigation. *See, e.g., In re Zyprexa Prods. Liab. Litig.*, 467 F. Supp. 2d at 262 (“Cooperation with state courts will continue to be stressed.”); *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 898105, at \*1 (E.D.N.Y. Apr. 16, 2006) (“Coordination and cooperation between state and federal courts has been encouraged.”); *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 197151 (E.D.N.Y. Jan. 30, 2006) (letter to state judges with *Zyprexa* cases suggesting coordination and cooperation); *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2004 WL 3520248, at \*4 (E.D.N.Y. Aug. 18, 2004) (directing defendant Lilly and Plaintiffs’ Steering Committee I to “confer regarding procedures for coordination of state court discovery with discovery in this MDL”).

A national system for resolving Medicare and Medicaid liens was approved. *See In re Zyprexa Prods. Liab. Litig.*, 451 F. Supp. 2d 458 (E.D.N.Y. 2006). All states and the federal government agreed to modify their lien demands to provide a national equitable system. *See In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 3501263, at \*1 (E.D.N.Y. Dec. 4, 2006) (“In compliance with this court’s instructions . . . all fifty states as well as the federal government have resolved their Medicare and Medicaid liens.”) (citation omitted).

On April 16, 2004, a class action was filed on behalf of individuals claiming personal injury based on, among other claims, Lilly’s failure to provide an adequate warning about the risks of *Zyprexa*. *See Ortiz v. Eli Lilly & Company*, No. 04-CV-1587 (E.D.N.Y.). A second and substantially similar class action was filed in this court on May 19, 2004. *See Tringali v. Eli Lilly & Company*, No. 04-CV-2104 (E.D.N.Y.). On September 15, 2004, Lilly and plaintiffs’ counsel in the two putative class actions entered into an agreement to execute stipulations of

dismissal of the class actions, with the effective date of dismissal to be November 1, 2004, or 167 days after the *Ortiz* action was filed. See Joint Memorandum of the Parties Regarding Stipulation of Voluntary Dismissal of Certain Claims, No. 04-MD-1596, Docket Entry No. 80, Attach. 2.

Discovery and negotiations were overseen in part by a court-appointed special discovery master and four special settlement masters. In November 2005, Lilly, without conceding liability, entered into a settlement covering some 8,000 individual plaintiffs. See *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2005 WL 3117302 (E.D.N.Y. Nov. 22, 2005). The settlement resolved virtually all cases then pending in the MDL, along with some state cases. See *id.*

An attorneys' fee structure for many cases was ordered, capping fees at 20% of recovery in smaller, lump-sum claims, and at 35% of recovery in other claims. See *In re Zyprexa Prods. Liab. Litig.*, 424 F. Supp. 2d 488 (E.D.N.Y. 2006). Costs related to the individual cases and charged to individual settling plaintiffs were limited. See *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 2443248 (E.D.N.Y. Aug. 24, 2006). Counsel for some 2,000 individual plaintiffs filed an appeal of an order capping fees, see *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2007 WL 2340789 (E.D.N.Y. Aug. 17, 2007), which is now pending before the Court of Appeals for the Second Circuit. The magistrate judge allocated funds from a first common benefit fund after reviewing the first Plaintiffs' Steering Committee's ("PSC I") applications. See *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2007 WL 805793 (E.D.N.Y. Mar. 15, 2007). Allocation of funds has been substantially completed for PSC I.

Following an influx of thousands of new cases, in January 2007 the parties announced another round of settlements, which are nearing completion. A second common benefit fund was established to compensate members of a second PSC for their work. *See In re Zyprexa Prods. Liab. Litig.*, 467 F. Supp. 2d at 262.

Four motions for summary judgment by Lilly in individual *Zyprexa* cases were decided in June 2007. Three of those motions were denied and one was granted based on application of the statute of limitations, which barred that plaintiff's claim. *See Souther, et al. v. Eli Lilly & Co.*, 489 F. Supp. 2d 230 (E.D.N.Y. 2007).

A class action has been brought on behalf of third-party payor institutional plaintiffs that include pension funds, labor unions, and insurance companies that cover their members' health benefits; they have covered payments for Zyprexa prescriptions. Mail fraud under the Racketeer Influenced and Corrupt Organizations Act ("RICO") is alleged, *see* 18 U.S.C. § 1964, predicated on overpricing supported by excessive claims of utility as well as disavowal of adverse secondary effects of the drug, primarily weight gain and diabetes. That class has been certified. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69, 201 (E.D.N.Y. 2008). Individual plaintiffs who bought, or paid a portion of the purchase price for, Zyprexa for their own use also sought class action status on a similar theory. Certification of this individual payor class action was denied. *See id.* at 201-02.

Many state attorneys general have sued on behalf of their states' citizens seeking reimbursement for overpayments for Zyprexa made with state and federal funds via state Medicaid programs and other remedies based upon state law grounds. Currently pending in this court are actions on behalf of the citizens of several states. A putative *qui tam* action by a

whistleblower representing California was dismissed. Order, *California ex rel. Jaydeen Vincente v. Eli Lilly & Co.*, Apr. 23, 2008, No. 08-CV-600, Docket Entry No. 84. Most state attorney general cases have been settled.

In March 2008, Lilly reportedly settled with the state of Alaska during trial in a related case. See Alex Berenson, *Alaska Suit Against Lilly Is Settled*, N.Y. Times, Mar. 26, 2008, at C1 (reporting the settlement agreement reached after three weeks of trial before the case went to the jury). That state's lawsuit sought reimbursement for the medical costs of Alaska Medicaid patients who developed diabetes while taking Zyprexa; the state's claim to recover costs associated with Lilly's off-label promotion of Zyprexa was dismissed before trial. See Alex Berenson, *Lilly Executive Discussed Off-Label Uses for Drug*, N.Y. Times, Mar. 15, 2008, at C1. Some of the materials introduced in that trial are available as part of the public record. Other Zyprexa settlements have followed. See Alex Berenson, *33 States to Get \$62 Million in Zyprexa Case Settlement*, N.Y. Times, Oct. 7, 2008, at B7.

Some of Lilly's shareholders have filed suit because of the decline in share price. See *In re Eli Lilly & Co. Securities Litig.*, No. 07-CV-1310 (E.D.N.Y.). This litigation has been dismissed on statute of limitations grounds. See *In re Zyprexa Prods. Liab. Litig.*, 549 F. Supp. 2d 496 (E.D.N.Y. 2008).

Current shareholders have sued in this court in the form of three separate shareholder derivative actions. See *Waldman v. Taurel*, No. 08-CV-560 (E.D.N.Y.); *City of Taylor Employees Retirement System v. Taurel*, No. 08-CV-1554 (E.D.N.Y.); *Robins v. Taurel*, No. 08-CV-1471 (E.D.N.Y.). Similar cases are pending in other courts. Settlement negotiations are ongoing.

Additional cases transferred to the multidistrict litigation are being managed by a special master, who is tracking settlements, setting timelines for discovery and the adjudication of dispositive motions, and scheduling trial dates. *See* Case Management Order No. 32, 04-MD-1596, Docket Entry No. 2072, Mar. 3, 2009. Several cases originally set for trial have been settled or withdrawn. Individual actions originating in the Eastern District of New York have been placed on an expedited discovery and motion schedule so that trial on those actions may, if necessary, move forward without undue delay.

A series of summary judgment motions by Lilly in individual Zyprexa user actions are now pending. The court has ruled on the parties' *Daubert* motions challenging proposed expert testimony in a number of these and other cases. *See In re Zyprexa Prods. Liab. Litig.*, 04-MD-1596, 2009 WL 1357236 (E.D.N.Y. May 12, 2009) (ordering the exclusion of plaintiffs' proposed expert testimony in twenty cases); *see In re Zyprexa Prods. Liab. Litig.*, 04-MD-1596, 2009 WL 1322286, (E.D.N.Y. May 12, 2009) (approving plaintiffs' proposed expert testimony in two cases); *In re Zyprexa Prods. Liab. Litig.*, 04-MD-1596, 2009 WL 1322292 (E.D.N.Y. May 12, 2009) (approving defendant's proposed expert testimony); *Souther*, 489 F. Supp. 2d at 281-91 (denying plaintiffs' and defendant's *Daubert* motions to exclude expert testimony).

### III. Facts

#### A. Contents and Use of Zyprexa

Zyprexa's active ingredient is olanzapine, one of a class of medications known as "atypical" or "second generation" antipsychotics. It was approved for use in treating schizophrenia and acute manic episodes associated with bipolar disorder by the United States

Food and Drug Administration ("FDA") in 1996. In 2004, the FDA also approved Zyprexa for the treatment of bipolar disorder generally.

B. Labeling and Warnings to Patients and Medical Professionals

1. *FDA Labeling and "Dear Doctor Letter"*

The 1996 Zyprexa package insert accompanying the drug disclosed information about possible side effects of administration of olanzapine based on clinical trials. The insert provided, in part, the following information:

Adverse Events Occurring at an Incidence of 1% or More Among Olanzapine-Treated Patients in Short-Term, Placebo-Controlled Trials - - [The tables] enumerate[] the incidence, rounded to the nearest percent, of treatment-emergent adverse events that occurred during acute therapy (up to 6 weeks) of schizophrenia in 1% or more of patients treated with olanzapine (doses  $\geq$  2.5 mg./day) where the incidence in patients treated with olanzapine as greater than the incidence in placebo-treated patients.

The prescriber should be aware that the figures in the tables and tabulations cannot be used to predict the incidence of side effects in the course of usual medical practice where patient characteristics and other factors differ from those that prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses, and investigators. The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and nondrug factors to the side effect incidence in the population studies.

Zyprexa Package Insert, dated October 1, 1996, at 11 (emphasis in original).

Two tables in the insert provided the results of placebo-controlled clinical studies of olanzapine-treated patients. The data indicates that, over a six-week administration of Zyprexa, six percent of olanzapine-treated patients reported weight gain, while only one percent of the placebo-treated patients reported weight gain. *Id.* at 12-16.

For several years, this information on the insert remained substantially the same insofar as it provided physicians information on reported weight gain-related adverse events. During this period, the results of longer-term studies and clinical experience with Zyprexa and competing drugs became widely known. *See* Part III.B.IV, *infra*.

In May 2000, the FDA undertook an analysis of the incidence of diabetes and hyperglycemia in patients using atypical antipsychotics. The director of the FDA's Division of Neuropharmacological Drug Products ("DNPD") requested additional safety information about Zyprexa from Lilly. In its letter, the FDA cited post-marketing reports of diabetes-related adverse events associated with Zyprexa use. In response, Lilly provided the FDA with clinical studies, data analysis, and case report reviews. The parties disagree about whether the information given by Lilly to the FDA was complete and accurate.

On September 11, 2003, the FDA announced it would require a warning about risks of hyperglycemia and diabetes mellitus and treating precautions to appear in the package insert of all atypical antipsychotics, including Zyprexa. Designed for prescribing doctors, the label noted that epidemiological studies and other information indicated that the relationship between the drug and hyperglycemia and diabetes was not yet fully understood. It reads as follows:

**WARNINGS**

**Hyperglycemia and Diabetes Mellitus**

Hyperglycemia, in some cases extreme and associated with ketoacidosis or hypersomolar coma or death has been reported in patients treated with atypical antipsychotics including Zyprexa. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However,

epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics studied. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available . . . .

Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing.

The label did not mention weight gain or diabetes in the “warning to patients” section.

Lilly added the FDA-required language to the Zyprexa label on September 16, 2003. It issued a press release announcing the label change on September 17, 2003. At the FDA’s request, on March 1, 2004, Lilly sent a “Dear Doctor” letter to physicians in the United States informing them of the 2003 label change.

2. *Consensus Statement of American Diabetes Association and Other Learned Groups*

In November 2003, the American Diabetes Association, American Psychiatric Association, American College of Clinical Endocrinologists, and the North American Association for the Study of Obesity convened a consensus development conference (the “ADA consensus conference”) on the subject of the association between antipsychotic drugs and diabetes. An eight-member panel heard presentations from fourteen experts drawn from the fields of psychiatry, obesity, and diabetes; FDA representatives; and atypical antipsychotic drug

manufacturers. The panel reviewed most of the relevant peer-reviewed English language scientific articles.

The ADA consensus conference concluded that Zyprexa and Clozaril posed an increased risk of diabetes as compared to other atypical antipsychotic drugs. The consensus statement produced by the conference declared that these relative risks as well as advantages of the individual drugs for individual patients in a heterogeneous population "should . . . influence drug choice." In part, its report concluded:

There is considerable evidence, particularly in patients with schizophrenia, that treatment with [atypical antipsychotics] can cause a rapid increase in body weight in the first few months of therapy that may not reach a plateau even after 1 year of treatment. There is, however, considerable variability in weight gain among the various [atypical antipsychotics] . . . Clozapine [Clozaril] and olanzapine [Zyprexa] . . . produce the greatest weight gain.

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Despite limitations in study design, the data consistently show an increased risk for diabetes in patients treated with clozapine [Clozaril] or olanzapine [Zyprexa] compared with patients not receiving treatment with [first generation antipsychotics] or with other [atypical antipsychotics]. The risk in patients taking risperidone and quetiapine is less clear; some studies show an increased risk for diabetes, while others do not. The two most recently approved [atypical antipsychotics], aripiprazole and ziprasidone, have relatively limited epidemiological data, but available clinical trial experience with these drugs has not shown an increased risk for diabetes.

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[T]he risks of obesity, diabetes, and dyslipidemia have considerable clinical implications in this patient population and should . . . influence drug choice. Even for those medications associated with an increased risk of metabolic side effects, the benefit to specific patients could outweigh the potential risks. For example, clozapine [Clozaril] has unique benefits for treatment-

refractory patients and those at significant risk for suicidal behavior. Since treatment response in many psychiatric conditions is heterogeneous and unpredictable, physicians and patients can benefit from the availability of a broad array of different therapeutic agents.

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These three adverse conditions [obesity, diabetes, and dyslipidemia] are closely linked, and their prevalence appears to differ depending on the [atypical antipsychotic] used. Clozapine [Clozaril] and olanzapine [Zyprexa] are associated with the greatest weight gain and highest occurrence of diabetes and dyslipidemia. Risperidone and quetiapine appear to have intermediate effects. Aripiprazole and ziprasidone are associated with little or no significant weight gain, diabetes, or dyslipidemia, although they have not been used as extensively as other agents. The choice of [atypical antipsychotic] for a specific patient depends on many factors. The likelihood of developing severe metabolic disease should also be an important consideration.

3. *FDA March 2007 Letter*

On March 28, 2007, the FDA raised concerns about the adequacy of Zyprexa's warning label in a letter to Lilly.

[W]e are concerned that the labeling is deficient with regard to information about weight gain, hyperglycemia, and hyperlipidemia that is associated with olanzapine [Zyprexa] use . . . . Our overall goal is to improve labeling with regard to these findings so that clinicians will be better informed on what the risks are for their patients. They cannot make reasonable treatment decisions until they have such information. We do not feel that current labeling for . . . Zyprexa provides sufficient information on these risks, and we fully intend to insure that . . . labels are enhanced with the best available information to characterize these risks.

4. *Findings on Medical Community's Knowledge of Zyprexa's Risks*

A universally applicable date from which the statute of limitations is to be considered to run on an individual Zyprexa user's claim has not been determined. Numerous events represent

moments at which a patient, health care provider, institution, or the medical community at large arguably discovered that the cause of an alleged injury may have been the administration of Zyprexa. The evidence in this mass litigation, including medical records and the depositions of numerous doctors, suggests that it was widely known and understood in the late 1990s among treating and prescribing physicians that weight gain may follow the administration of Zyprexa. The association between weight gain and heightened risks of diabetes was also broadly recognized by that time.

Formal events include the September 2003 Zyprexa label change and contemporaneous press release, the 2003 consensus statement of the American Diabetes Association, and the March 2004 "Dear Doctor" letter distributed nationwide to physicians by Lilly.

In its June 2007 memorandum, order, and judgment on four motions for summary judgment, this court found that, for purposes of those motions, the March 2004 "Dear Doctor" letter would be considered the latest possible date on which members of the medical community knew or should have known about Zyprexa's obesity- and diabetes-related risks to patient health. *See Souther*, 489 F. Supp. 2d at 278. In *Souther*, applying the relevant "learned intermediary" doctrine, it was determined that Souther's claim was barred by the statute of limitations:

Diabetes developed and Zyprexa was prescribed [to plaintiff Cusella] years before the September 2003 label change. *At least from the date of March 2004 Dear Doctor letter, the causal connection between Zyprexa and diabetes was known to Dr. Ganime, Cusella's treating physician.* Since Lilly's duty to warn ran to Dr. Ganime rather than Cusella, it became Dr. Ganime's duty from that point onwards to disclose to Cusella that Zyprexa might exacerbate his diabetes, and that it may have been the impetus behind Cusella's insulin-dependancy in the first place.

Dr. Ganime's medical records and deposition testimony . . . show that Cusella was warned numerous times about the link between Zyprexa and diabetes. While the pre-label change warnings Dr.

Ganime received from Lilly *may* not have been adequate to absolve Lilly of liability to Cusella, those warnings Cusella received from Dr. Ganime following the label change placed him on notice that use of Zyprexa might have worsened his diabetes and caused him to become insulin-dependent.

*Measured either against the date Cusella developed diabetes — August 1999 — or the latest possible date Dr. Gamine was aware of the potential causal connection between Zyprexa and diabetes — March 2004 —* Pennsylvania's two year statute of limitations had run on Cusella's claim before he filed this suit in April of 2006.

*Id.* at 278 (emphasis added).

The March 1, 2004 date represents the “latest possible date” which prescribing physicians and, in effect, their patients are deemed aware of the potential causal connection between Zyprexa and diabetes and from which the statute of limitations may run as to any individual plaintiff. Nevertheless, a fact-specific analysis is necessary for each case to determine when the plaintiff – whether independently or by operation of the learned intermediary doctrine – knew the potential causal connection between Zyprexa and adverse health effects. The facts in many individual cases indicate a much earlier date of discovery for purposes of the statute of limitations. *See, e.g.*, Appendices A-D of *Souther*, 489 F. Supp. 2d 230 (including over 1500 pages of relevant depositions demonstrating doctors' awareness of Zyprexa's association with patient weight gain).

C. Medical History and Treating Physician's Decision to Prescribe Zyprexa

While Lilly argues that there is no evidence that the deceased ingested Celexa and no scientific basis for an adverse Zyprexa-Celexa interaction—thereby negating any claim of failure to warn—the court prefers to analyze the motion on the theory of the bar created by the learned intermediary doctrine. It has considered—but not relied upon—the fact that plaintiffs also

pursued state court claims in Louisiana against Mr. Folse's psychiatrist, Dr. Edgardo Concepcion, alleging that his decision to prescribe Zyprexa together with Celexa deviated from the standard of care. *See* Def.'s Local Rule 56.1 Statement of Undisputed Material Facts ("Def.'s SUF"), Ex. 2 at 9. The Louisiana medical review panel, a physician panel established under Louisiana law to preliminarily assess medical malpractice claims, *see* La. Rev. Stat. § 40:1299.39.1, disagreed, concluding that Celexa and Zyprexa are "commonly prescribed together and thus not a deviation from the standard of care." Def.'s SUF, Ex. 3 at 1; *see also id.*, Ex. 4 at 67 (transcript of deposition testimony of Randall Tackett, Ph.D., agreeing that Zyprexa and Celexa are commonly prescribed together).

Mr. Folse began psychiatric treatment with Dr. Concepcion in January 2002. *Id.*, Ex. 2 at 23-24; Ex. 21 at 09. Before then, Mr. Folse had received mental health treatment from several primary care physicians and a counselor for symptoms that included chronic worrying and significant anxiety. *See id.*, Ex. 22 (notes from counselling sessions detailing medical treatment by various physicians). Mr. Folse had previously tried and failed to find relief from several psychiatric medications for his anxiety and depression, including Zoloft, Paxil, Effexor, Buspar, and Remeron. *Id.*, Ex. 23 at 14, 16, 18; Ex. 24.

At their first meeting, Dr. Concepcion diagnosed Mr. Folse with attention deficit hyperactivity disorder ("ADHD"), depressive disorder, and anxiety disorder with panic attacks. *Id.*, Ex. 2 at 34-35; Ex. 21 at 11. The treating physician prescribed Adderall XR for Mr. Folse's ADHD. *Id.*, Ex. 2 at 35. Dr. Concepcion also suspected that Mr. Folse suffered from bipolar disorder, and prescribed Zyprexa to treat his "mood changes, . . . rapid thoughts, [and to] help[] him sleep." *Id.*, Ex. 2 at 35-36.

Mr. Folse responded well to Zyprexa. His symptoms improved. *Id.*, Ex. 2 at 39-43. When Mr. Folse returned for his second visit with Dr. Concepcion on February 7, 2002, Mr. Folse displayed noticeable improvements while taking his medications. Dr. Concepcion noted that Mr. Folse's "mind [was] resting better at night" and he was "not as hyper during the day." *Id.*, Ex. 21 at 12. He prescribed Ativan to be used as needed for anxiety, and he increased the Adderall XR dose. *Id.*, Ex. 2 at 36; Ex. 21 at 12. By his third visit with Dr. Concepcion in March 2002, Mr. Folse was "doing good" with "no physical complaints"; his "stress level, mood and anxiety [had] been more manageable." *Id.*, Ex. 21 at 12.

On August 20, 2002, after seven months on Zyprexa, Mr. Folse reported to Dr. Concepcion that he was feeling "more depressed, withdrawn," and lacking in motivation. *Id.*, Ex. 21 at 14. He also reported that his work and family were sources of stress. *Id.* Dr. Concepcion directed Mr. Folse to begin taking 20 mg of Celexa daily, in addition to Adderall and Zyprexa. *Id.*, Ex. 21 at 15. It is alleged that Dr. Concepcion provided Mr. Folse with a 28-day supply of Celexa samples. *Id.*, Ex. 1 ¶ 12 (plaintiffs' Petition for Damages).

Dr. Concepcion testified that he never observed any indication that Mr. Folse experienced side effects of Zyprexa toxicity, such as over-sedation, slurred speech, weight gain, yellowness or jaundice of the skin, nausea or vomiting, or extrapyramidal symptoms. *Id.*, Ex. 2 at 40-46.

When Dr. Concepcion added Celexa to Mr. Folse's treatment, he was aware of the interaction profiles of Celexa and Zyprexa. *Id.*, Ex. 2 at 17-18. He understood that Celexa is a weak inhibitor of the CYP2D6 pathway and that Zyprexa is metabolized by the CYP2D6 pathway. *Id.*

Q. [Y]ou were aware when you prescribed olanzapine [Zyprexa] and citalopram [Celexa] in combination to Mr. Folse that in-vitro studies had indicated that the CYP1A2 and CYP2D6

isoforms were inhibited to some extent by citalopram; is that correct?

A. Yes, that's correct.

Q. Okay. And you also were aware that the CYP1A2 and CYP2D6 isoforms were responsible for metabolizing olanzapine, is that correct?

A. Yes, sir.

*Id.*, Ex. 2 at 17.

Dr. Concepcion understood the interaction profiles of both Celexa and Zyprexa, and he knew that neither the products' respective package inserts nor the scientific literature suggested an impediment to prescribing both medicines to Mr. Folse—because there is no reason to suspect an adverse connection between the drugs:

Q. Okay. And that information was available to you before you prescribed olanzapine and citalopram in combination to Mr. Folse; is that correct?

A. That's correct.

Q. Okay. And you didn't view those facts related to the isoforms we just discussed as a basis not to prescribe it together, correct?

A. That's correct.

*Id.*, Ex. 2 at 18.

Q. [I]f Celexa is added to the medication regime of someone already taking olanzapine, . . . from a pharmacology/toxicology standpoint, that new drug could inhibit the metabolism or oxidation of the Zyprexa?

A. There have been some experiments about that, and the inhibition or disinhibition is not significant to alter the metabolism of the medication.

*Id.*, Ex. 25 at 106-07.

Dr. Concepcion also testified that both Lilly and Forest provided adequate warnings for Zyprexa and Celexa:

Q. Okay. Do you think that the manufacturers of olanzapine and citalopram . . . should have told you anything different or additional about the potential interaction between the two drugs?

A. I don't think so. I think they're fair in giving information to all the doctors are using or possibly using those medications.

Q. Okay. So you're satisfied with the warnings and information you received from the manufacturers of olanzapine and citalopram?

A. Yes, sir.

Q. Okay. And in that regard, you feel the warnings and information that your received were adequate?

A. Yes.

*Id.*, Ex. 2 at 18-19.

If a patient today displayed symptoms identical to those of Mr. Folse, Dr. Concepcion testified that he would have "no hesitation" in prescribing Zyprexa and Celexa in combination for that patient:

Q. [I]f you had a patient . . . walk in your office with a clinical presentation identical to that of Mr. Folse on August 20, 2002, when you originally prescribed citalopram to him, would you still prescribe citalopram knowing that [he or she] already was taking olanzapine?

A. Yes, sir.

Q. Okay. No hesitation?

A. No hesitation.

*Id.*, Ex. 2 at 15-16.

On the evening of September 7, 2002, Mr. Folse visited with a friend, and they drank beer together. *Id.*, Ex. 26. The friend testified that Mr. Folse showed no effects of Zyprexa toxicity that evening, such as difficulty speaking, slurring words, sedation, drowsiness, fatigue, or difficulty breathing. *Id.*, Ex. 27 at 35-37. After Mr. Folse returned home, he died in his sleep sometime before 12:30 pm on September 8. *Id.*, Ex. 26.

A police investigation and autopsy followed. *Id.*, Exs. 28 & 29. Neither the police nor the coroner found Celexa during their death scene investigations. *Id.*, Exs. 28 & 30. A toxicology screening performed during the autopsy detected the presence of Zyprexa, but not Celexa. *Id.*, Ex. 31.

#### **IV. Law**

##### **A. Summary Judgment Standard**

Summary judgment is appropriate only if “there is no genuine issue as to any material fact . . . [in which case] the moving party is entitled to a judgment as a matter of law.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986); *see also Mitchell v. Washingtonville Central School District*, 190 F.3d 1, 5 (2d Cir. 1999). Summary judgment is warranted when after construing the evidence in the light most favorable to the non-moving party and drawing all reasonable inferences in its favor, there is no genuine issue as to any material fact. Fed. R. Civ. P. 56(c); *see Anderson*, 477 U.S. at 247-50, 255; *Sledge v. Kooi*, 556 F.3d 137, 140 (2d Cir. 2009).

The burden rests on the moving party to demonstrate the absence of a genuine issue of material fact. *Goenaga v. March of Dimes Birth Defects Found.*, 51 F.3d 14, 18 (2d Cir. 1995);

*see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). If the moving party appears to meet this burden, the opposing party must produce evidence that raises a material question of fact to defeat the motion. *See Fed. R. Civ. P. 56(e)*. This evidence may not consist of “mere conclusory allegations, speculation or conjecture[.]” *Cifarelli v. Village of Babylon*, 93 F.3d 47, 51 (2d Cir. 1996); *see also Delaware & Hudson Ry. v. Consolidated Rail Corp.*, 902 F.2d 174, 178 (2d Cir. 1990) (“Conclusory allegations will not suffice to create a genuine issue.”).

B. Choice of Law

A multidistrict litigation transferee court applies the choice of law and statute of limitations rules of the state in which the action was filed. *Menowitz v. Brown*, 991 F.2d 36, 40 (2d Cir. 1993) (citing *Van Dusen v. Barrack*, 376 U.S. 612 (1964)). Because the instant action was originally commenced in Louisiana, the principles on choice of law from that state apply. All the relevant events took place in Louisiana, whose substantive law applies.

C. Louisiana State Law – Learned Intermediary Doctrine

In the prescription medicine products liability context, Louisiana applies the learned intermediary doctrine to inadequate warning claims. *See Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 265 (5th Cir. 2002). “Under this doctrine, a drug manufacturer discharges its duty to consumers by reasonably informing prescribing physicians of the dangers of harm from a drug.” *Id.* To establish a pharmaceutical manufacturer inadequately warned about its medicine, a plaintiff must prove: (1) that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that was not otherwise known to the physician and (2) that this failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff’s injury. *Id.* at 265-66. “[T]he plaintiff must show that a proper warning would have

changed the decision of the treating physician, *i.e.*, that but for the inadequate warning, the treating physician would not have used or prescribed the product.” *Ferguson v. Proctor & Gamble Pharms., Inc.*, 353 F. Supp. 2d 674, 679 (E.D. La. 2004) (internal quotation marks omitted).

The learned intermediary defense is an “aspect of proportionality that shifts at least some of the burden of protecting patients from pharmaceutical manufacturers to treating physicians . . . . [T]he learned intermediary rule cannot be viewed as an all-or-nothing regulation that absolves the manufacturer, shifting the onus entirely to the treating physician, but its force in ameliorating liability for damages of the manufacturers cannot be ignored.” *Souther*, 489 F. Supp. 2d at 244.

There is a strong trend in prescription drug failure-to-warn cases to reiterate and apply this well established doctrine. *See, e.g., Motus v. Pfizer Inc.*, 358 F.3d 659, 661 (9th Cir. 2004) (holding that a product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician) (citing *Plummer*, 819 F.2d at 358-59); *Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767 (S.D. Tex. 2008) (granting summary judgment for defendant upon finding that prescribing physician was aware of Zyprexa’s suicide-related risks that an adequate warning would have provided and that plaintiff had presented no evidence physician would not have prescribed Zyprexa had defendant provided him with an alternate warning label), *aff’d*, No. 08-40170, 2009 WL 837325 (5th Cir. Mar. 30, 2009); *Allgood v. GlaxoSmithKline PLC*, No. 06-3506, 2008 WL 483574, at \*3 (E.D. La. Feb. 20, 2008) (granting summary judgment for defendant because plaintiff had failed to show (1) that defendant did not adequately warn the physician of a risk associated with the drug

that was not otherwise known to the physician and (2) that the “failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff’s injury”), *aff’d sub nom. Allgood v. SmithKline Beecham Corp.*, No. 08-30329, 2009 WL 6465285 (5th Cir. Mar. 13, 2009).

#### **V. Application of Law to Facts**

Plaintiffs cannot demonstrate causation: No different warning would have changed Dr. Concepcion’s decision to prescribe Zyprexa and Celexa in combination to Mr. Folse. Before Dr. Concepcion prescribed to Mr. Folse, he understood the interaction profiles of Celexa and Zyprexa, and correctly recognized the potential, but medically insignificant, danger of inhibition. *See supra* at 18-19. The Zyprexa label advises physicians of the process by which the body metabolizes Zyprexa. Dr. Concepcion testified that he considered the warnings and information he received to be adequate. *See supra* at 19.

Soon after Mr. Folse’s death, plaintiffs sued Dr. Concepcion and accused him of causing the death by prescribing Celexa and Zyprexa together. Despite that accusation, Dr. Concepcion testified that if a patient today displayed the same symptoms and Mr. Folse, he would have “no hesitation” in prescribing Celexa knowing that the patient was already taking Zyprexa. Def.’s SUF, Ex. 2 at 15-16.


Plaintiffs argue that Dr. Concepcion’s diagnoses and prescription decisions were incorrect, and that therefore his credibility is at issue. However, plaintiffs have offered no legitimate basis to question the credibility of Dr. Concepcion’s testimony regarding his own state of mind and reasoning at the time. Given Dr. Concepcion’s testimony, no reasonable juror could find that a different warning would have changed his prescription decisions.

**VI. Conclusion**

Defendant's motion for summary judgment is granted. There is no basis for a claim against Forest Laboratories, Inc. and Forest Pharmaceuticals, Inc., or against Dr. Concepcion.

The case as a whole is dismissed. No costs or disbursements.

SO ORDERED.

  
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Jack B. Weinstein  
Senior United States District Judge

Date: October 9, 2009  
Brooklyn, New York